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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,412	03/08/2006	Norio Sakuragawa	0760-0344PUS1	5108

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BIRCH STEWART KOLASCH & BIRCH  
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EXAMINER
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KIM, TAEYOON

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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12/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,412	<b>Applicant(s)</b> SAKURAGAWA ET AL.	
	<b>Examiner</b> TAEYOON KIM	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,4 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 6-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2009 has been entered.

Applicant's amendment and response filed on 11/2/2009 has been received and entered into the case.

Claims 1, 2 and 5 have been canceled, claims 6-12 are newly added, and claims 3, 4 and 6-12 are pending and have been considered on the merits. All arguments have been fully considered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hung et al. (of record) in light of Whittle et al. (of record) and Tseng (US 6,152,142).

Hung et al. teach mesenchymal stem cells capable of differentiating into bone cells (see abstract) obtainable from placenta or umbilical cord (see par. 26), and a method of culturing mesenchymal stem cells in an osteogenic culture medium to differentiate the mesenchymal stem

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cells into osteoblasts (see par. 37, Example 4). Hung et al. also teach a method of tissue replacement (considered as transplantation) using mesenchymal stem cells (see abstract), and transplanting mesenchymal stem cells (see par. 32).

Although Hung et al. do not particularly disclose the MSCs are derived from amniotic mesenchymal cell layer, it is well known in the art that amnion is a part of placenta as evidenced by the teaching of Whittle et al. (abstract and p.395) or Tseng, teaching that human amniotic membrane is obtained from human placenta (see abstract), and thus the MSCs of Hung et al. derived from human placenta would inherently contain MSCs from human amniotic membrane which contains the amniotic mesenchymal cell layer (see col. 3, lines 49-53), and derived from the amniotic membrane.

Thus, the reference anticipates the claimed subject matter.

In the response to the previous office action, applicant alleged that one skilled in the art would recognize that the placenta contains tissues other than amnion, and the proportion of the bone stem cells found in a mixture of cells collected from the entire placenta would be smaller than the proportion found in a mixture of cells collected from only the mesenchymal layer of the amnion as in the claimed invention. This argument is not persuasive since it relies on the feature which is not claimed in the instant invention. The current invention does not require whether the proportion of the cells collected to be specific percentage or any particular range, rather the claims disclose a method of preparing bone cells from the collected bone stem cells.

Furthermore, the instant claims do not disclose that the bone stem cells are isolated or purified from the source. As indicated in the office action above, the anticipation rejection is drawn to

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claims 3, 4 and 10 which do not require a step of selection or separation of bone stem cells positive for SB-10.

The method of Hung et al. to isolate MSCs from placenta or umbilical cord, which comprises amnion and thus, amniotic membrane, according to Whittle et al. and Tseng, would inherently carry out the claimed method step of isolating bone stem cells, and the method of osteogenic differentiation taught by Hung et al. is the same method step of generating bone cells of the claimed invention. Thus, Hung et al. in light of Whittle et al. and Tseng anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung et al. (supra) in view of Whittle et al. (of record), Tseng (supra) and Bruder et al. (1997; IDS ref.).

Hung et al. in view of Whittle et al. and Tseng teach the subject matter disclosed in claims 3, 4 and 10, and thus render them obvious (see above).

Hung et al. in view of Whittle et al. and Tseng do not teach the method step of using SB-10 antigen to separate cells collected from the mesenchymal cell layer of human amnion.

Bruder et al. teach SB-10 antigen and monoclonal antibody having a specific affinity to SB-10 antigen expressed on human osteogenic cells (i.e. mesenchymal stem cells), and a method

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of using them in isolating osteogenic MSCs from bone marrow via a flow cytometry (see entire document).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try SB-10 antigen and a monoclonal antibody to SB-10 to isolate osteogenic MSCs for the method of osteogenic differentiation taught by Hung et al.

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) “The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was “obvious to try.” *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.” See also M.P.E.P. §2141.

It is considered that the limitation drawn to the bone cells expressing alkaline phosphatase (claim 8) or the bone cells not expressing antigen SB-10 (claim 6) is considered as an inherent property of the cells produced by the claimed method, and it is not an active step required to be carried out in the claimed method, and therefore, adds nothing to the patentability or substance of the claim. Therefore, this phrase does not limit the claim.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/  
Primary Examiner, Art Unit 1651